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# COMPOSITION FOR ORAL CAVITY

[KŌKŌ YŌ SŌSEIBUTSU]

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/1[1]

(54) [Title of the Invention]

Composition for Oral Cavity

/2[1]

[Scope of Patent Claims]

[Claim 1] A composition for an oral cavity wherein the following components (A), (B), and (C):

(A) 0.02 ~ 0.7 wt % of a fluorine ion-supplying component (in terms of fluorine atom),

(B) 0.1 ~ 5 mol/kg of an acidic compound having a pKa (25°C) of 2.5 ~ 6.0 and its salt, and

(C) 5 ~ 90 wt % of water

are contained, and the pH of the composition itself or a 30 wt % aqueous solution of the composition is 3 ~ 5.5.

[Claim 2] The composition for an oral cavity as set forth in Claim 1, wherein (D) an anionic surfactant is further contained.

[Claim 3] The composition for an oral cavity as set forth in Claim 1 or 2, wherein the acids of component (B) are one or more acids selected from lactic acid, acetic acid, citric acid, malic acid, succinic acid, tartaric acid, and adipic acid.

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[1]Numbers in the margin indicate pagination in the foreign text.

[Detailed Description of the Invention]

[0001]

[Technical Field of the Invention] The present invention relates to a composition for an oral cavity having a whitening effect in the case of applying it to the tooth surface and, in more detail, to a composition for an oral cavity capable of imparting whiteness and gloss to the tooth surface.

[0002]

[Prior Art and Problems to Be Solved by the Invention] Coloration of the teeth is dependent on exogenous coloration, wherein a coloring matter adheres to the tooth surface due to odontolith, dental plaque, smoking, or habitual consumption of food and drinks such as coffee or tea, and endogenous coloration, wherein the dentin is colored due to aging and its color can be seen through the highly transparent enamel or when the enamel itself is colored due to the use of medicines, such as tetracycline and so on, in a period of forming the enamel. Accordingly, it is necessary to treat not only the exogenous coloration but also the endogenous coloration for thoroughly whitening the teeth.

[0003] As a means for whitening the teeth, various physical or chemical methods have been reported before. As physical methods, a method wherein coloring matters are removed by

polishing as well as using n-butyl ether or butyl butyrate, or the like (Japan Unexamined Patent 01-203316, Japan Unexamined Patent 01-104004) and a method wherein the tone of the teeth is improved by covering them with a ceramic veneer or the like are given. As chemical methods, a method of accelerating re-calcification with a composition for the oral cavity formulated with hydroxyapatite (Japan Unexamined Patent 01-305020, Japan Unexamined Patent 09-202718), a method of oxidation bleaching with a peroxide (Japan Unexamined Patent 06-8248), and so on have been known. More recently, a tooth whitening effect composition obtained by formulating a self-curing calcium phosphate and a fluorine compound with a peroxide has also been reported (Japan Unexamined Patent 11-116421).

[0004] However, the conventional methods have such problems that the whitening effect is not said to be sufficient, as well as others. In the method of using a ceramic veneer, the dentine must be shaved, and thus guidance and treatment made by a dentist is necessary for its use. Then, operation applied by a specialist must be expensive.

[0005] An object of the present invention is to provide a composition for the oral cavity that can easily beautify/whiten teeth in daily life without requiring the guidance and treatment of a dentist.

[0006]

[Means for Solving the Problem] The inventors acquired such knowledge that white, smooth, and glossy teeth are obtained without requiring operation applied by a specialist by supplying a fluorine ion in a buffer solution system kept to a specific pH. They also clarified that calcium fluoride was slowly formed on the tooth surface or in the outer layer of the tooth under this condition. Accordingly, the inventors made an earnest investigation into a composition capable of generating calcium fluoride in the oral cavity and persistently supplying it to the tooth surface. Consequently, they discovered that a composition that was formulated by combining a fluorine ion-supplying component and an acidic compound having a constant dissociation index of hydrogen ion and its salt and regulating it so that the pH of the composition itself or a 30 wt % aqueous solution of the composition exhibited 3 ~ 5.5 could whiten teeth. When this composition is applied to the oral cavity, this condition is completely consistent with a condition for efficiently forming calcium fluoride on the tooth surface by keeping a pH exhibiting a predetermined solubility or higher for hydroxyapatite or fluoroapatite and a very low solubility for calcium fluoride. Such formation of calcium fluoride is considered to be a reason

for the very excellent whitening effect of the invented composition on teeth.

[0007] The present invention provides a composition for the oral cavity wherein the following components (A), (B), and (C):

(A) 0.02 ~ 0.7 wt % of a fluorine ion-supplying component (in terms of fluorine atom),

(B) 0.1 ~ 5 mol/kg of an acidic compound having a pKa (25°C) of 2.5 ~ 6.0 and its salt, and

(C) 5 ~ 90 wt % of water

are contained, and the pH of the composition itself or a 30 wt % aqueous solution of the composition is 3 ~ 5.5.

[0008]

[Embodiment of the Invention] The fluorine ion-supplying component (component (A)) is not specially limited if it is a substance usable in the oral cavity; for instance, inorganic fluorides such as sodium fluoride, potassium fluoride, ammonium fluoride, lithium fluoride, monofluorophosphate (for example, sodium monofluorophosphate, potassium monofluorophosphate, ammonium monofluorophosphate), and so on, organic fluorides such as amine fluoride, and so on are given, and sodium fluoride, ammonium fluoride are preferable among them from the viewpoints of safety, solubility, flavor, and so on. In these compounds, a monofluorophosphate is not a fluorine ion and is supplied first;

then, a fluorine ion is slowly supplied into the oral cavity. For instance, even if sodium fluoride is formulated, when a calcium salt or a zinc salt or the like exists in the composition from the beginning, it reacts with the fluorine ion to reduce the supply of fluorine ion, and therefore formulation

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of these multivalent metal salts is undesirable in the present invention.

[0009] In the invented composition for the oral cavity, not only one but also two or more of these fluorine compounds can be formulated for use.

(A) The content of the fluorine ion-supplying component is 0.02 ~ 0.7 wt % (simply expressed as "%" hereinafter) of the entire composition of the present invention in terms of fluorine atom in the fluorine ion-supplying component from the viewpoint of whitening effect on the teeth and the reinforcement of dentine, and more preferably 0.02 ~ 0.2 % for household uses from the viewpoint of preventing the toxicity of fluoride caused by erroneous drinking.

[0010] pKa (25°C) of the acid compounds of component (B) is 2.5 ~ 6.0, more preferably 2.5 ~ 5.0, and even more preferably 3 ~ 4.5. Here, the buffer action of compounds having a pKa of less than 2.5 at pH ≈ 3 ~ 5.5 is not sufficient; therefore, efficient

generation of calcium fluoride does not proceed and a sufficient whitening effect on the teeth cannot be obtained. With compounds having a pKa of more than 6.0, a composition with a desirable pH exhibiting solubility for hydroxyapatite or fluoroapatite is difficult to obtain, and thus a sufficient whitening effect is not obtained. If the pH is below 3, its harmfulness in embrittling the teeth is a concern. pKa is an inverse number of the logarithm of the acid dissociation constant (for example, it has been described in *Chemical Handbook, Fundamentals;* revised 2nd ed., p993, Maruzen Inc., 6th printing, September 20, 1981; *Chemical Handbook, Fundamentals;* revised 4th ed., p317, Maruzen Inc., September 30, 1993, and so on.). As these acid compounds, for instance, monobasic acids such as formic acid, acetic acid, propionic acid, and so on; dibasic acids such as oxalic acid, succinic acid, fumaric acid, maleic acid; hydroxycarboxylic acids such as lactic acid, glycolic acid, tartaric acid, malic acid, citric acid, ascorbic acid; acidic amino acids such as glutamic acid, asparaginic acid; keto acids such as levulinic acid; aromatic carboxylic acids such as benzoic acid, salicylic acid, and so on are given.

[0011] One or more acids selected from lactic acid, acetic acid, citric acid, malic acid, succinic acid, tartaric acid, and adipic acid are more preferable among them.

[0012] As salts of the acid compounds, alkali metal salts such as sodium salts and potassium salts are given. These salts of acid compounds may be added in preparation of the invented composition; however, an acid compound and an alkali may also be formulated separately to form a buffer system of the acid compound and its salt in the composition. Sodium hydroxide, potassium hydroxide, and so on are typical alkalis, but the alkalis are not limited to them so long as they promote ionization of an acid present in an acid type.

[0013] 0.1 ~ 5 mol/kg of an acid compound and its salt in component (B) (as the total amount of an acid compound and its salt in the invented composition, in other words, acid and salt) is preferably contained from the viewpoint of achieving a beautifying/whitening effect. The molar ratio of acid to salt is preferably 10:1 ~ 1:10 to impart a buffer capacity.

[0014] As is described above, a multivalent ion of metal such as zinc and calcium essentially cannot be contained to keep the effect of the invented composition for the oral cavity. This is because calcium fluoride cannot be generated under an acid condition if a fluoride ion cannot be quickly supplied. Thus, calcium of the teeth is eluted, the gloss is lost though the teeth are whitened, and the harmfulness to the teeth due to long-term use is a concern. A buffer solution system contained

in the invented composition for the oral cavity means that it is a composition containing (C) water. The content of water is preferably 5 ~ 90 % in the invented composition. A state of aqueous solution is essentially necessary to display the buffer capacity. Water is also necessary to supply a fluorine ion immediately.

[0015] In the invented composition for the oral cavity, the pH of the composition itself or a 30 wt % aqueous solution of the composition is 3 ~ 5.5; when the invented composition is applied to the oral cavity, it is important in that the composition keeps the solubility for hydroxyapatite or fluoroapatite and has a low solubility for calcium fluoride. From this, the pH is preferably 3.5 ~ 5.0. A real use concentration is assumed under the condition of 30 wt %.

[0016] An anionic surfactant (D) is contained in the invented composition for the oral cavity, and this is preferable for enhancing the whitening effect. As the anionic surfactants, salts of higher alkyl sulfate, salts of N-alkyl sarcosine, and higher fatty acid monoglyceride monosulfate are preferable. The carbon number of the alkyl group or fatty acid residue of these surfactants is preferably 8 ~ 24, and more preferably 8 ~ 18. As salts of these surfactants, alkali metal salts, ammonium salts, and organic amines are preferable. 0.1 ~ 5 %, especially 0.2 ~ 2

%, of the surfactants is preferably contained in the invented composition from the viewpoint of the whitening effect on the teeth.

[0017] In addition to the above components, for instance, foamer, foaming assistant, abrasive, wetting agent, binder, extender, sweetener, preservative, bactericide, drug-effect ingredient, adhesive, pigment, colorant, perfume, and so on can be properly contained in the invented composition for the oral cavity. The inclusion of polyethylene glycol, being a whitening component, or others used before is also not limited.

[0018] The invented composition can be prepared in the dosage forms of solution, gel, or paste; however, polyethylene glycol, propylene glycol, glycerin, sorbitol, multitol, xylitol, lactitol, erythritol, and so on can be contained in any of these dosage forms with in the role of a wetting agent, thickener, or the like. As thickeners for a solution-like composition or gelling agents for a gel-like composition, as well as binders in the case of a paste-like composition, sodium carboxymethyl cellulose, hydroxy-

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ethyl cellulose, carboxyvinyl polymer, xanthan gum, carageenan, sodium alginate, hydroxypropyl cellulose, guaiac gum, sodium chondroitin sulfate, and so on can be contained. Particularly,

when the salt concentration is high for a buffer solution system, nonionic polymers, in other words, hydroxyethyl cellulose, guaiac gum, hydroxypropyl cellulose, and so on can also be contained.

[0019] The invented composition for the oral cavity can be produced by an ordinary method, for instance, in the case of toothpaste, it can be produced by measuring ingredients, such as purified water, a wetting agent, a binder, a flavor, a preservative, a sweetener, a buffer solution, a drug-effect ingredient of fluorine ion-supplying component and, if necessary, other drug-effect ingredients by formulated amounts, then mixing the ingredients according to predetermined production conditions, swelling the binder, further adding an abrasive and a foamer, then defoaming and mixing. If necessary, regulation of the pH may also be carried out after the composition is prepared.

[0020] The invented composition for the oral cavity thus obtained exhibits solubility for hydroxyapatite and fluoroapatite, and therefore colored hydroxyapatite on the tooth surface is dissolved. The invented composition has low solubility for calcium fluoride, and therefore it reacts with a fluorine ion and a calcium ion in saliva to efficiently form calcium fluoride on the tooth surface. In this manner, the

calcium fluoride layer formed on the tooth surface has acid resistance and suppresses elution of calcium ion and/or phosphoric acid ion from the tooth surface. Moreover, the layer is not peeled or shaved by the action of a toothbrush or a brushing level mechanical action and has excellent retentivity on the teeth. Accordingly, the invented composition for the oral cavity is useful as a composition for the oral cavity for beautifying/whitening the teeth, because white, smooth, and glossy teeth are easily obtained. Moreover, as is shown in the embodiment examples described later, the invented composition is also considered effective on hyperesthesia from the fact that pain of panels with hyperesthesia generated in the case of tooth grinding and keeping cold water or the like in the mouth is alleviated with the invention samples. It is also expected that the invented composition is probably effective on precaution of dental cavities because of a large incorporated amount of fluorine.

[0021]

[Embodiment examples] Embodiment example 1

1 M aqueous solutions containing 0.23 % of sodium fluoride were prepared with acids having different pKa, and the pH was regulated to 4 with sodium hydroxide. The solubility was determined, and then teeth of cattle (the surface was mirror

polished) photographed beforehand were dipped in the aqueous solutions for 24 hr, respectively, and the color of the teeth was compared with that of the teeth before the treatment. In a method for comparison, the photographs of the teeth before and after the treatment were shown to 20 panels. Teeth that the panels thought were whitened were labeled as "O", and teeth that the panels though were unchanged were labeled as "×". At this time, the teeth that panels felt were mat due to the treatment were estimated as "×" though they were whitened. If more than half of the teeth were "O", the aqueous solution was judged to be effective, otherwise it was judged to be ineffective.

[0022] The solubility was determined as follows. Namely, A composition was diluted with ion exchange water so as to become 30 wt %. The concentrations of phosphorus and calcium in a solution were quantified beforehand with a colorimetry reagent and then subtracted. Hydroxyapatite (HAP), fluoroapatite (FAP) and $CaF_2$ powders were added to 100 mL of the solution, respectively. It was stirred for 24 hr with a magnetic stirrer, and then a solid matter was removed by filtration. The concentrations of phosphorus and calcium in this solution were quantified with a colorimetry reagent.

[0023] The references of solubility for HAP or FAP was taken as 200 mg/L or more of calcium and 300 mg/L or more of

phosphorus. A composition satisfying either condition was taken as “O”. The reference of solubility for $CaF_2$ was taken as 150 mg/L or less of calcium, a composition satisfying this condition was taken as “O”. In Table 1, compositions satisfying all the references of solubility were shown as “O”. As colorimetry reagents for calcium and phosphorus, Calcium Test Wako (for quantification of calcium, made by Wako Pure Reagents Co.) and P test Wako (for quantification of inorganic P) were used.

[0024] Consequently, as shown in Table 1, compositions obtained by adding acids having pKa of 2.5 ~ 6.0 to 0.02 ~ 0.7 % sodium fluoride and adding an alkali to make pH 3 ~ 5.5 exhibited good solubility for hydroxyapatite or fluoroapatite and low solubility for calcium fluoride, and they also had an excellent whitening effect on the teeth.

[0025]

[Table 1]

| Added acid | | pKa | Solubility | Whitening effect |
|---|---|---|---|---|
| Comparative example | Hydrochloric acid | -8 | O | × |
| | Sulfuric acid | 1.99 | O | × |
| | Phosphoric acid | 2.15 | O | × |
| Embodiment example | Citric acid | 2.9 | O | O |
| | Tartaric acid | 2.99 | O | O |
| | Malic acid | 3.24 | O | O |
| | Lactic acid | 3.66 | O | O |

| | | | | |
|---|---|---|---|---|
| | Acetic acid | 4.56 | ○ | ○ |

[0026] Embodiment example 2

Aqueous solutions shown in Table 2 were prepared, the solubility and the whitening effect were similarly estimated as Embodiment example 1. As a result, it was clarified that if an anionic surfactant was formulated, the whitening effect was enhanced.

[0027]

[Table 2]

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(wt %)

| Ingredient | Embodiment example | | | Comparative example |
|---|---|---|---|---|
| | 2-1 | 2-2 | 2-3 | 2-1 |
| Sodium lauryl sulfate | 1 | | 1 | |
| Sodium N-myristyl sarcosine | | 1 | | |
| Phosphoric acid | | | | 5 |
| Citric acid | 10 | | | |
| Tartaric acid | | 5 | | |
| Malic acid | | | 5 | |
| Lactic acid | | | | |
| Sodium fluoride | 0.3 | 0.1 | 0.21 | 2 |
| Sodium hydroxide | proper | proper | proper | proper |
| Purified water | balance | balance | balance | balance |
| pH | 3.5 | 4 | 4.5 | 4 |

| | | | | |
|---|---|---|---|---|
| Solubility | ○ | ○ | ○ | ○ |
| Whitening effect | ○ | ○ | ○ | × |

[0028] Embodiment example 3

Dentrifice shown in Table 3 was prepared by ordinary methods, and the solubility in 30 % aqueous solutions thereof were similarly determined as embodiment example 1. The whitening effect was also similarly determined as embodiment example 1 (dipped for 24 hr in the dentrifice). The results are shown in Table 3. Toothpastes shown in Table 3 (embodiment example 3-1 ~ embodiment example 3-4) were used for 1 month in place of toothpastes used in daily life by 10 panels who were conscious of hyperesthesia. As a result, all the panels using the toothpastes of embodiment example 3-1 ~ embodiment example 3-4 estimated that the extent of hyperesthesia (the extent of pain generated in case of keeping cold water in the mouth) was alleviated.

[0029] [Table 3]

| 成分 | 実施例 | | | | | 比較例 | | |
|---|---|---|---|---|---|---|---|---|
| | 3-1 | 3-2 | 3-3 | 3-4 | 3-5 | 3-1 | 3-2 | 3-3 |
| | 歯磨剤 | 歯磨剤 | 歯磨剤 | 歯磨剤 | 洗口液 | 歯磨剤 | 歯磨剤 | 洗口液 |
| 乳酸 | 5 | | | 5 | 3 | 7 | | |
| クエン酸 | | 10 | | 5 | | | | |
| リンゴ酸 | | | 10 | | | | | |
| 塩酸 | | | | | | | 2 | |
| ソルビトール70%溶液 | 35 | 35 | 35 | 35 | 10 | 35 | 1 | 10 |
| プロピレングリコール | 5 | 5 | 5 | 5 | | 5 | 5 | |
| p-オキシ安息香酸メチル | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| サッカリンナトリウム | 0.1 | 0.1 | 0.1 | 0.1 | | 0.1 | 0.1 | |
| ラウリル硫酸ナトリウム | 1 | | | 1 | | 1 | | |
| ポリオキシエチレン硬化ヒマシ油 | | 1 | 1 | | 0.5 | | 1 | |
| フッ化ナトリウム | 0.21 | 0.21 | 0.21 | 0.21 | 0.042 | 0.21 | 0.21 | 0.042 |
| ヒドロキシエチルセルロース | 0.5 | 0.5 | 0.5 | 0.5 | | 0.5 | 0.5 | |
| カルボキシメチルセルロース | 0.5 | 0.5 | 0.5 | 0.5 | | 0.5 | 0.5 | |
| 含水ケイ酸 | 15 | 15 | 15 | 15 | | 15 | 15 | |
| 香料 | 1 | 1 | 1 | 1 | 0.2 | 1 | 1 | |
| pH調整剤 (NaOH) | 適量 | 適量 | 適量 | 適量 | 適量 | 適量 | 適量 | 適量 |
| 精製水 | バランス | バランス | バランス | バランス | バランス | バランス | バランス | バランス |
| 計 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| pH | 4 | 4 | 4 | 4.5 | 4.5 | 7 | 4 | 7 |
| 溶解性 | ○ | ○ | ○ | ○ | ○ | × | ○ | × |
| 実口くさ | ○ | ○ | ○ | ○ | ○ | × | × | × |

(left side)

(wt %)

| Ingredient | Embodiment example | | | | |
|---|---|---|---|---|---|
| | 3-1 | 3-2 | 3-3 | 3-4 | 3-5 |
| | Tooth-paste | Tooth-paste | Tooth-paste | Tooth-paste | Mouth-wash |
| Lactic acid | 5 | | | 5 | 3 |
| Citric acid | | 10 | | 5 | |
| Malic acid | | | 10 | | |
| Hydrochloric acid | | | | | |
| Sorbitol 70 % solution | 35 | 35 | 35 | 35 | 10 |
| Propylene glycol | 5 | 5 | 5 | 5 | |
| Methyl p-oxybenzoate | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sodium saccharin | 0.1 | 0.1 | 0.1 | 0.1 | |
| Sodium lauryl sulfate | 1 | | | 1 | |
| Polyoxyethylene hardened castor oil | | 1 | 1 | | 0.5 |
| Sodium fluoride | 0.21 | 0.21 | 0.21 | 0.21 | 0.042 |
| Hydroxyethyl cellulose | 0.5 | 0.5 | 0.5 | 0.5 | |

| | | | | | |
|---|---|---|---|---|---|
| Carboxymethyl cellulose | 0.5 | 0.5 | 0.5 | 0.5 | |
| Hydrated silicic acid | 15 | 15 | 15 | 15 | |
| Perfume | 1 | 1 | 1 | 1 | 0.2 |
| pH regulator (NaOH, HCl) | proper | proper | proper | proper | proper |
| Purified water | balance | balance | balance | balance | balance |
| Total | 100 | 100 | 100 | 100 | 100 |
| pH | 4 | 4 | 4 | 4.5 | 4.5 |
| Solubility | ○ | ○ | ○ | ○ | ○ |
| Whitening effect | ○ | ○ | ○ | ○ | ○ |

[Table 3] (contd.)

(right side)

(wt %)

| Ingredient | Comparative example | | |
|---|---|---|---|
| | 3-1 | 3-2 | 3-3 |
| | Tooth-paste | Tooth-paste | Mouth-wash |
| Lactic acid | 7 | | |
| Citric acid | | | |
| Malic acid | | | |
| Hydrochloric acid | | 2 | |
| Sorbitol 70 % solution | 35 | 1 | 10 |
| Propylene glycol | 5 | 5 | |
| Methyl p-oxybenzoate | 0.1 | 0.1 | 0.1 |
| Sodium saccharin | 0.1 | 0.1 | |
| Sodium lauryl sulfate | 1 | | |
| Polyoxyethylene hardened castor oil | | 1 | |
| Sodium fluoride | 0.21 | 0.21 | 0.042 |
| Hydroxyethyl cellulose | 0.5 | 0.5 | |
| Carboxymethyl cellulose | 0.5 | 0.5 | |
| Hydrated silicic acid | 15 | 15 | |
| Perfume | 1 | 1 | |
| pH regulator (NaOH, HCl) | proper | proper | proper |

| | | | |
|---|---|---|---|
| Purified water | balance | balance | balance |
| Total | 100 | 100 | 100 |
| pH | 7 | 4 | 7 |
| Solubility | × | ○ | × |
| Whitening effect | × | × | × |

[0030]

[Effects of the Invention] If the invented composition for the oral cavity is used, white, smooth, and glossy teeth are easily obtained.